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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Antonio Guarna et al.	Confirmation No.:	5376
Serial No.:	10/518,689	Art Unit:	1617
Deposited:	December 17, 2004	Examiner:	Kevin J. Capps
Customer No.:	21559		
Title:	Pharmaceutical Compositions for the Treatment of Diseases Related to Neurotrophines		

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REPLY TO RESTRICTION REQUIREMENT

In reply to the Restriction Requirement that was mailed in connection with the above-captioned patent application on March 31, 2006, Applicants elect the invention of Group I, with traverse.

The claims readable on the elected invention are 22-26, 41, and 42 (all in part) drawn to compounds of formula (I) as listed in claim 41 and 42, and to pharmaceutical compositions containing the compounds of formula (I) as active principle as defined in claim 22.

The Restriction Requirement is traversed for the following reasons.

First, Applicants note that the present application is a national stage application filed under 35 U.S.C. § 371. Thus, consistent with M.P.E.P. 1893.03(d), Applicants respectfully submit that PCT Unity of Invention standards apply, rather than U.S. Restriction practice.

Under PCT Unity of Invention standards, claims to different categories (e.g., products and methods of use of such products) can be included in the same application, provided that the contribution over the prior art of the products corresponds to the contribution of the methods of use over the prior art. PCT Administrative Instructions, Annex B, Part 1(e). As is discussed below, Applicants submit that the presently claimed products (pharmaceutical compositions) and methods (methods of use of the compositions in treating the enumerated diseases) have corresponding contributions over the prior art. Thus, at a minimum, these claims should be examined together in the present application.

A corresponding contribution that the claimed pharmaceutical compositions and methods of use make over the prior art is that they both relate to the first suggestion to use the compounds specified in the claimed compositions in pharmaceutical practice. The two documents cited by the Examiner, Machetti et al., Organic Letters 2(25):3987-3990, 2000, and Guarna et al., J. Org. Chem. 64:7347-7364, 1999, do not make reference to any possible therapeutic use of compounds of formulae (I), (II), and (III), nor to pharmaceutical compositions containing them as active principles. In particular, please note that the document Machetti et al. discloses some compounds having the 3-aza-bicyclo[3.2.1.]octane core, which are excluded from the present product claims 41 and 42. No reference is made by Machetti et al. as to their possible application in therapy or to pharmaceutical compositions containing them as active principles. The only reference made by Machetti et al. as to the use of these compounds is as catalysts for use in, e.g., transestrerification reactions (see Machetti et al., page 3987, col. 2, last paragraph).

As to Guarna et al., we note that this document describes the synthesis and characterization of compounds having the 3-aza-bicyclo[3.2.1.]octane core, but therapeutic application of such compounds has not been investigated at all. Rather, a reference is made to their use for the synthesis of modified peptides (see Guarna et al., page 7347, very last sentence of Abstract). As with the compounds disclosed by Machetti et al., discussed above, the compounds disclosed by Guarna et al. also have been excluded from the product claims 41 and 42 of the present application.

Thus, the presently claimed pharmaceutical compositions and methods, which are based on the present Applicants' first suggestion to use the compounds of these compositions and methods in pharmaceutical practice, share a corresponding special technical feature over the prior art. Applicants therefore respectfully request that the Restriction Requirement be withdrawn.

We further submit that the Restriction Requirement cannot be based on documentary purposes, in order to narrow the field of search, as all of the alleged independent inventions fall into the same class and subclass. Moreover, the present application as filed has already been examined, together with the two cited prior art documents in question, by the International Searching Authority, which found it as complying with the PCT unity of invention requirements.

Applicants further submit that, even under U.S. Restriction practice, which does not apply here, M.P.E.P. § 821.04 provides that, where product and process claims are separated into different restriction groups, and an Applicant elects product claims for examination, rejoinder of the process claims may be obtained as a matter of right, if the process claims that depend from or otherwise include all of the limitations of the product claims. Thus, if applied in the present case, even Restriction practice would provide a mechanism for rejoinder of the claims that the

Examiner is now requiring be separated. Thus, under either standard, the present pharmaceutical composition claims and method claims should, at least at some point, be examined in a single application.

Finally, Applicants would like to make clear that the election set forth above of claims 22-26, 41, and 42 for prosecution in the present case is made to meet the Restriction Requirement, but without prejudice with respect to claims directed to the compounds of formulae (II) and (III) and to the related pharmaceutical compositions and therapeutic methods, which Applicants reserve the right to claim in divisional applications.

In conclusion, in view of the above, Applicants request reconsideration of the Restriction Requirement. Applicants request that at least the claims directed to compositions comprising compounds (I) and methods of treating specified diseases by administering the compositions comprising the compounds (I) as active principles be maintained in the same application. Thus, Applicants request that the claims of Groups I, IV, VII, X, XIII, XVI, XIX, XXII, XV, XVIII, etc. (including all other Groups referring to compounds I until Group CLXXX), be brought together in the present application for prosecution.